

### **REMARKS**

This is a full and timely response to the non-final Office Action mailed by the U.S. Patent and Trademark Office on August 13, 2009. Claim 11 is amended. Claims 1-10, 13-20, 24, 25 and 27-38 are canceled. Claims 11, 12, 21-23, 26 and 39-46 are pending in the present application. The subject matter of amended claim 11 is illustrated in FIGs. 2C, 7A, and 7B and described in the related detailed description of Applicants' original specification. Therefore, no new matter is introduced.

In view of the foregoing amendments and following remarks, reconsideration and allowance of the present application and claims are respectfully requested.

#### **Response to Claim Rejections under 35 U.S.C. §103 – Claims 11, 12, 21-23, 26, 39-46**

##### **A. Statement of the Rejection**

Claims 11, 12, 21-23, 26, 39-41, 43, 45 and 46 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent Application Publication 20020004246 to Daniels et al. (hereinafter *Daniels*) in view of U.S. Patent No. 6,217,744 to Crosby (hereinafter *Crosby*) further in view of U.S. Patent No. 5,371,687 to Holmes II et al. (hereinafter *Holmes*) and U.S. Patent No. 5, 602,040 to May (hereinafter *May*).

Claims 42 and 44 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Daniels*, *Crosby*, *Holmes* and *May*, as applied to claim 11, further in view of U.S. Patent Application Publication 2003/0174743 to Cliche et al. (hereinafter *Cliche*).

##### **B. Discussion of the Rejection**

For a claim to be properly rejected under 35 U.S.C. § 103, the Examiner should set forth in the Office action: the relevant teachings of the prior art relied upon, the difference or differences in the claim over the applied reference(s), the proposed modification necessary to arrive at the claimed subject matter and an explanation as to why the claimed invention would have been obvious to one of ordinary skill in the art at the time the invention was made. It is well settled law that a *prima facie* case of obviousness must teach or suggest all the claimed limitations.

Regarding the requirement to teach or suggest all the claim limitations, MPEP § 2143.03 states “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). ‘All words in a claim must be considered in judging the patentability of that claim against the prior art.’ *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants’ independent claim 11, as amended, includes at least one element that is not disclosed, taught or suggested by the proposed combination of *Daniels*, *Crosby*, *Holmes* and *May*. More specifically, the proposed combination fails to disclose, teach or suggest at least “a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module for receiving electrical power from a source external to the single-use module and for communicating information to a reusable module when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the circuit substrate.”

*May* is cited for the disclosure of an element that is no longer in claim 11, as amended. In addition, *May* does not remedy the failure of *Daniels*, *Crosby* and *Holmes* to disclose, teach or suggest at least Applicants’ claimed rapid diagnostic test system which includes a single-use module having a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module, among other features.

*Holmes* is cited for the disclosure of a terminal located on an external surface of the single use module for receiving electrical power and configured to be pluggably inserted into a receptacle of the reusable module for communicating test result signals. (See Office Action, page 6, first paragraph).

*Holmes* discloses a data processing module that includes a first multiple conductor connector and complimentary second multiple conductor connectors for connecting to the first multiple conductor connector when a respective housing is mated to the data processing module. (See *Holmes*, column 3, lines 5-10.) *Holmes*

(e.g., FIG. 2) includes slides 122 located on a glucose test station 40 that align a separate housing 124 when it is placed or otherwise arranged in close contact with the glucose test station 40. Power and signal connections are enabled via a connector socket 134 on the data collection separate housing 124 and a corresponding set of pins arranged on the glucose test station 40 (not shown). A connector socket 134 having multiple conductors, as disclosed in *Holmes*, does not disclose, teach or suggest a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module for receiving electrical power from a source external to the single-use module and for communicating information to a reusable module when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the circuit substrate.. Furthermore, *Holmes* does not remedy the failure of *Daniels*, *Crosby* and *May* to disclose, teach or suggest at least this feature of Applicants' claimed rapid diagnostic test system.

*Daniels* discloses immunochromatographic test strip assays which employ semiconductor nanocrystals as detectable labels and methods for detecting and quantifying one or more analytes of interest in a test sample using the assays. *Daniels* is entirely silent regarding the claimed "terminal arranged along at least one external surface of a substrate that extends through and beyond an external surface of a housing of the single-use module." Moreover, *Daniels* does not remedy the failure of *Crosby*, *Holmes* and *May* to disclose, teach or suggest at least this feature of Applicants' claimed rapid diagnostic test system.

*Crosby* discloses a device whereby power for the device comes from an electrochemical battery where a portion of the fluid sample itself becomes the electrolyte for the battery. Furthermore, the time of diffusion of the fluid into the battery provides the timing signal for activation of the system. Communication between the device and an information system is provided by a transponder system built into the device, which requires no direct electrical connection. (See *Crosby*, Abstract.)

*Crosby* is cited for its alleged disclosure of a single use module that is inserted into a receptacle of a reusable module for the communication of test signals and for receiving electrical power. See Office Action, page 5, first paragraph. Specifically,

the Office Action refers to column 8, lines 28-40 of *Crosby* as teaching a capacitor, which the Office Action alleges is an external terminal that receives power. Applicants disagree.

The capacitor disclosed in *Crosby* is not an external terminal. The word “external” describes the position or relation between an element and something else. *Crosby*’s diagnostic device contains a large value capacitor. The word, “contain” means to hold or include within. Power is coupled inductively to the diagnostic device and the capacitor contained within the diagnostic device stores sufficient energy to operate the electronics for an adequate time to perform the diagnostic test and store the results in a memory, which is read by the console. (See *Crosby* column 8, lines 28-40.)

In contrast with the capacitor disclosed in *Crosby*, which is contained within the diagnostic device, Applicants’ terminal is arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module for receiving electrical power from a source external to the single-use module. Thus, a capacitor arranged within a diagnostic device, which can receive and store an electrical charge, does not disclose, teach or suggest Applicants’ claimed terminal, which as recited in claim 11, is arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module for receiving electrical power from a source external to the single-use module and for communicating information to a reusable module when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the substrate.

The Office Action further indicates that *Crosby* teaches that while not preferable, it is possible to directly electrically connect the device to a reader for power supply and information gathering (column 6, lines 57-67). However, while *Crosby* indicates that a direct connection is possible, *Crosby* does not show, and is entirely silent regarding any structure that could enable a direct connection between a circuit substrate of a single use module and a reusable module. Accordingly, *Crosby* does not remedy the failure of *Daniels*, *Holmes* and *May* to disclose, teach or suggest at least Applicants’ claimed terminal arranged along at least one external surface of a

circuit substrate that extends through and beyond an external surface of a housing of the single-use module for receiving electrical power from a source external to the single-use module and for communicating information to a reusable module when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the substrate.

The proposed combination of *Daniels, Crosby, Holmes and May* does not disclose, teach or suggest at least Applicants' claimed rapid diagnostic test system which includes a single-use module having a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module. In addition, the proposed combination of *Daniels, Crosby, Holmes and May* does not disclose, teach or suggest a terminal with conductors layered along at least one external surface of a circuit substrate. For at least these separate and distinct reasons, the proposed combination *Daniels, Crosby, Holmes and May* fails to establish a *prima facie* case of obviousness with respect to Applicants' claim 11 for failure to disclose all features and elements recited in the claim. Accordingly, favorable reconsideration and withdrawal of the rejection of independent claim 11 under 35 U.S.C. §103(a) are respectfully requested.

Because independent claim 11 is allowable, dependent claims 12, 21-23, 26, 39-41, 43, 45 and 46, which depend directly or indirectly from allowable independent claim 11, are allowable. *In re Fine, supra*. Accordingly, favorable reconsideration and withdrawal of the rejection of dependent claims 12, 21-23, 26, 39-41, 43, 45 and 46 under 35 U.S.C. §103(a) are respectfully requested.

Applicants' dependent claims 42 and 44 depend (directly or indirectly) from independent claim 11. Consequently, claims 42 and 44 include all the features and elements of claim 11. Thus, dependent claims 42 and 44 each include "a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module for receiving electrical power from a source external to the single-use module and for communicating information to a reusable module when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the circuit substrate." The proposed

combination of *Daniels*, *Crosby*, *Holmes*, *May* and *Cliche* fails to disclose, teach or suggest at least this element of Applicants' claims 42 and 44.

As shown above, the proposed combination of *Daniels*, *Crosby*, *Holmes* and *May* does not disclose, teach or suggest all elements and features of Applicants' rapid diagnostic test system. Specifically, the proposed combination of *Daniels*, *Crosby*, *Holmes* and *May* does not disclose, teach or suggest "a terminal arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module." Furthermore, the proposed combination of *Daniels*, *Crosby*, *Holmes* and *May* fails to disclose, teach or suggest a terminal having conductors layered along the at least one external surface of the circuit substrate.

*Cliche* is cited for the disclosure of a diffractive grating, a thin film filter or lenses to filter large optical bandwidths. *Cliche* does not remedy the failure of *Daniels*, *Crosby*, *Holmes* and *May* to disclose, teach or suggest Applicants' claimed terminal, which as recited in claim 11, is arranged along at least one external surface of a circuit substrate that extends through and beyond an external surface of a housing of the single-use module for receiving electrical power from a source external to the single-use module and for communicating information to a reusable module when the terminal is insertably engaged in a receptacle of the reusable module, the terminal comprising conductors layered along the at least one external surface of the substrate. Thus, the proposed combination of *Daniels*, *Crosby*, *Holmes*, *May* and *Cliche* fails to establish a *prima facie* case of obviousness with respect to Applicants' dependent claims 42 and 44 for failure to disclose all features and elements recited in the claims. Accordingly, favorable reconsideration and withdrawal of the rejection of dependent claims 42 and 44 under 35 U.S.C. §103(a) are respectfully requested.

**CONCLUSION**

Applicants respectfully submit that pending claims 11, 12, 21-23, 26 and 39-46 are allowable and that the present application is in condition for allowance. Accordingly, a Notice of Allowance is respectfully solicited. Should the Examiner have any comments regarding the Applicants' response, Applicants request that the Examiner telephone Applicants' undersigned attorney.

Respectfully submitted,

**SMITH FROHWEIN TEMPEL  
GREENLEE BLAHA LLC  
D/B/A SENTRY LAW GROUP**

By: /Robert A. Blaha/  
Robert A. Blaha  
Registration No. 43,502  
(770) 709-0069